

JUL 17 2003

**Spinal Concepts, Inc.****Spinal Concepts, Inc. BacFix® Ti Spinal Fixation System****510(k) Summary****SUBMITTED BY**

Spinal Concepts, Inc.  
5301 Riata Park Court, Bldg. F  
Austin, TX 78727

**ESTABLISHMENT  
REGISTRATION NUMBER**

1649384

**CONTACT PERSON**

Primary  
Lisa Peterson  
Regulatory Affairs Specialist

Alternate  
David Hooper, Ph.D.  
Director, Clinical and  
Regulatory Affairs

Phone: 512-918-2700

Phone: 512-918-2700

Fax: 512-249-6734

Fax: 512-249-6734

**DATE PREPARED**

April 24, 2003

**CLASSIFICATION NAME**

KWQ: Spinal Intervertebral Body Fixation Orthosis. Class II.  
MNI: Pedicle Screw Spinal System. Class II.  
MNH: Spondylolisthesis Spinal Fixation Device System. Class II.  
KWP: Spinal Interlaminar Fixation Orthosis. Class II.  
NKB: Pedicle Screw Fixation System, Degenerative Disc Disease.  
Class III.

**COMMON NAME**

Rod and Screw Spinal Instrumentation

**PROPRIETARY NAME**

Spinal Concepts, Inc. BacFix® Ti Spinal Fixation System

**PREDICATE DEVICE**

- Spinal Concepts, Inc. BacFix® Ti Spinal Fixation System - (K013887).
- Spinal Concepts, Inc. InCompass Spinal Fixation System (K021564 and K023644).
- Blackstone™ Spinal Fixation System Staple & Washer - System Addition (K022605).
- DePuy-Acromed Moss Miami (K953925)
- Synthes USS (K000450)
- Medtronic Sofamor Danek CD Horizon (K001066)
- Medtronic Sofamor Danek TSRH (K982990)

**DEVICE DESCRIPTION**

The purpose of this abbreviated 510(k) Notification is to add Staple, Nut and Washer components to the BacFix Spinal Fixation System and also to expand the existing indications to include anterolateral spinal fixation. The Spinal Concepts, Inc. BacFix® Ti Spinal Fixation System Staple, Nut and Washer are titanium alloy devices (Ti-6Al-4V, per ASTM F136), which are non-sterile single use components. These devices function as a means of stabilizing the bone screw and to reduce negative effects of screw to bone purchase. These components are particularly desirable in an anterior spinal construct because load can be spread over a greater surface area.

## INDICATIONS

When intended for pedicle screw fixation, implants are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis). Levels of pedicle screw attachment for these indications range from T1 to the sacrum.

When intended for anterolateral screw, rod and or cable fixation of the T6-L5 spine the indications are degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), spinal stenosis, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor and failed previous fusion.

As a pedicle screw system, the BacFix® Spinal Fixation System is also intended for patients having Grade 3 or Grade 4 spondylolisthesis at L5-S1, when utilizing autologous bone graft, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is established. Levels of pedicle screw fixation for these indications range from L3 to the sacrum.

When intended for non-pedicle, posterior screw fixation of the non-cervical spine, the indications are:  
Idiopathic scoliosis.

Neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity.

Scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele.

Spinal fractures (acute reduction or late deformity).

Degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).

Neoplastic disease.

Spondylolisthesis.

Spinal Stenosis.

Failed previous fusion.

The cable-screws, cables and spinous process grommets are indicated for:

Defect of pars lateralis.

Spondylolisthesis.

Cables and spinous processes grommets may be used for interspinous wiring if additional stability is needed.

## MECHANICAL TEST DATA

Mechanical testing data was collected in accordance with FDA recognized standard ASTM F1717-96, to verify that the added components met established design requirements and performance standards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 17 2003

Ms. Lisa Peterson  
Regulatory Affairs Specialist  
Spinal Concepts, Inc.  
12012 Technology Blvd, Suite 100  
Austin, Texas 78727

Re: K030087  
Trade/Device Name: BacFix® Ti Spinal Fixation System  
Regulatory Number: 21 CFR 888.3070(b), 888.3050, 888.3060  
Regulation Name: Pedicle screw spinal system, Spinal interlaminar fixation  
orthosis, Spinal intervertebral body fixation orthosis  
Regulatory Class: III  
Product Code: NKB, MNI, MNH, KWP, KWQ  
Dated: April 24, 2003  
Received: April 25, 2003

Dear Ms. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

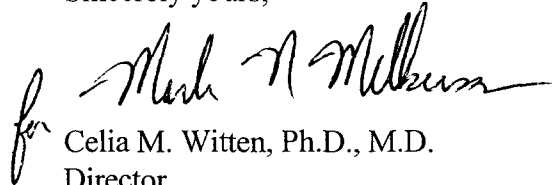
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.  
Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

Page 1 of 2

510(k) Number (if known):

K030087

Device Name:

Spinal Concepts, Inc. BacFix® Ti Spinal Fixation System

Indications for Use:

When intended for pedicle screw fixation, implants are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). Levels of pedicle screw attachment for these indications range from T1 to the sacrum.

When intended for anterolateral screw, rod and or cable fixation of the T6-L5 spine the indications are degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), spinal stenosis, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor and failed previous fusion.

As a pedicle screw system, the BacFix® Spinal Fixation System is also intended for patients having Grade 3 or Grade 4 spondylolisthesis at L5-S1, when utilizing autologous bone graft, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is established. Levels of pedicle screw fixation for these indications range from L3 to the sacrum.

When intended for non-pedicle, posterior screw fixation of the non-cervical spine, the indications are:

Idiopathic scoliosis.

Neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity.

Scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele.

Spinal fractures (acute reduction or late deformity).

Degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).

Neoplastic disease.

Spondylolisthesis.

Spinal Stenosis.

Failed previous fusion.

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K030087

Spinal Concepts, Inc.

5301 Riata Park Court, Bldg. F  
Austin, Texas 78727

Phone: 512-918-2700  
Fax: 512-249-6734

K030087

Page 2 of 2

The cable-screws, cables and spinous process grommets are indicated for:  
Defect of pars lateralis.  
Spondylolisthesis.

Cables and spinous processes grommets may be used for interspinous wiring if additional stability is needed.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter: \_\_\_\_\_  
(Optional Format 1-2-96)

*for Mark N. Melleson*  
\_\_\_\_\_  
(Division Sign-Off)

Division of General, Restorative  
and Neurological Devices

510(k) Number K030087